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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,688	01/11/2001	Wolfgang Heil	PLOVIN-2A	7991

23599 7590 08/21/2008

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
08/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/757,688	HEIL ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *173-192,195-230,233 and 234* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *173-192,195-230,233 and 234* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/20/06;6/12/06;9/29/06;5/21/07;5/21/07;5/25/07 (total 8 pages).

DETAILED ACTION

Receipt of response dated 6-29-07, IDS dated 4-20-06, 6-12-06, 5-21-07, 9-29-06 and 5-25-07 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-29-07 has been entered.

Claims 173-192, 195-230, 233 and 234 are pending in the instant application.

Response to Arguments

2. Applicant's arguments with respect to claims 173-192, 195-230, 233 and 234 have been considered and persuasive. However, the following new grounds of rejection replaces the rejections made previously of record:

Double Patenting

Double Patenting Claims 173-192, 195-230, 233 and 234 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-49 of U.S. Patent No. 6,869,941 in view of US 6,787,531. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Although the method of treating a disease, disorder or symptom issued in the above patent is broader in scope than the instant method claims, the issued claims of

US '531 are overlapping in scope with that of the instant claims because the dosage regimen of estrogen and drospirenone of the issued claims follow the same pattern as that of the instant regimen to achieve the claimed method. By definition, the effective amount of drospirenone for achieving the above regimen (and hence the method) of the issued claims involves micronized drospirenone having the same surface area and particle sizes as that of the instant claims and also has the same dissolution pattern as claimed in the instant application. Thus, the method of the patented as well as the instant claims involves the same composition and hence the instant method would have been obvious for one of an ordinary skill in the art at the time of the instant invention from the patented claims. Further, while the patented claims do not recite the specific dissolution profiles and the particle size distribution, US '531 teaches a composition comprising the same DSRP and estrogen i.e., estradiol for the same purpose as that of the instant claims as well as the claims of US 941. '531 teaches micronized DSRP with the particle size distribution recited in col. 3, L 40-50, where no particle is greater than 20 microns and teaches instant limitation of less than 2% particles are more than 30 microns (col. 3, L 4-25). For the specific release rates see col. 3, L 4-25, which recites the same release rates as that claimed with the combination of DSRP and estrogen. For the dosages and the regimen of administering DSRP and estrogen, '531 teaches the same amounts and the cycles of administering the combination of compounds and hence it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ micronized DSRP, in particular, in the size distribution taught by 531 in the composition of US 941 because '531 suggests that the

composition containing micronized DSRP in the above particle size distribution, dosages and further in combination of estradiol improves the bioavailability of the combination drugs by providing fast/rapid dissolution (examples).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/

Primary Examiner,
Art Unit 1611
August 18, 2008